

REMARKS

Claims 16-17, 19-20, and 24-26 have been canceled as drawn to a non-elected invention. Claims 3, 9, 11 and 12 have been amended to clarify the invention. In particular, claims 3 and 11 have been amended to delete the phrase “naturally occurring”. Claim 3 has been amended in the preamble of the claim to recite “An isolated polynucleotide encoding a polypeptide ...”. Claim 3 has been further amended at step d) to recite an immunogenic fragment of the polypeptide of SEQ ID NO:2 “which may be used for the production of an antibody that binds to a polypeptide of SEQ ID NO:2”. Claim 9 has been amended to depend from only claim 3, and claim 11 has been amended to recite the additional limitation that a polynucleotide sequence at least 90% identical to a polynucleotide sequence of SEQ ID NO:4 further encode a polypeptide having thioredoxin activity. Claim 12 has been amended to recite a “polynucleotide probe” comprising at least 60 contiguous nucleotides of a polynucleotide of claim 11, and to further identify the target of said probe as a polynucleotide which is “the complete complement of a polynucleotide of claim 11”. Claim 46 has been amended to recite “An isolated polynucleotide ...”. Support for the amendment to claim 11 is found in the specification at, for example, page 13, lines 19-25, which identifies the polypeptide of SEQ ID NO:2, encoded by the polynucleotide of SEQ ID NO:4, as a thioredoxin protein, and at page 42, lines 3-10, which describes an assay for measuring thioredoxin activity. Support for the amendment to claim 12 is found in the specification, for example, at page 11, lines 5-9 which describes oligonucleotide probes from 6 to 60 nucleotides, and at page 8, lines 6-8 which defines “complete complementarity” as an exact match between two sequences. No new matter is added by these amendments, and entry of the amendments is requested.

Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

I. Status of Application, Amendments, and/or Claims

The Examiner stated that the amendment filed on December 22, 2003 has been entered in full. Claims 3, 4 and 9 have been amended. Claims 3-9, 11-17, 19, 20, 24-28 and 46 are pending. Claims 3-7, 9, 11, 12 and 46 are under consideration.

It is further noted that claim 1 is listed as “canceled” in the pending claims, but stated that the claim is amended at page 7 of Applicants remarks filed on December 22, 2003. Clarification

is requested. Applicant acknowledges that claim 1 has been canceled as indicated at page 2 of the response, and that the recitation of claim 1 as "pending" at page 7 was in error.

II Priority

The Examiner stated that in view of Applicants arguments about utility of the present invention, the Examiner agrees that the claimed subject matter is entitled to the priority date, June 30, 1998 which is the filing date of 09/107,248.

III Withdrawn Objections an/or Rejections

The Examiner stated that the following objections and rejections have been withdrawn in view of Applicants amendments and remarks:

The rejection of claims 3-7, 9, 11, 12 and 46 under 35 U.S.C. § 101 for lack of utility,

The rejection of claims 3-7, 9, 11, 12 and 46 under 35 U.S.C. § 112, first paragraph regarding a lack of enablement based on a lack of utility,

The rejection of claims 11 and 46 under 35 U.S.C. § 112, second paragraph,

The rejection of claims 3, 4, 6, 7, 9, 11 and 12 under 35 U.S.C. § 102(b) as anticipated by Kato et al. (2000), and

The objection of claims 3 and 4 for being dependent on unelected claims.

IV 35 U.S.C. § 112, First Paragraph, Rejection of Claims 3, 6, 7, 9, 11 and 12 (Enablement)

The Examiner has maintained the rejection of claims 3, 4, 6, 7, 9, 11 and 12 under 35 U.S.C. § 112, first paragraph as set forth in the previous Office Action mailed September 24, 2003, because Applicants have not addressed the rejection of scope of enablement.

(1) The Examiner stated that claim 3(d) recites an immunogenic fragment of a polypeptide having an amino acid sequence of SEQ ID NO:2. Since an antibody produced by an immunogenic fragment of SEQ ID NO:2 does not necessarily bind to the protein of SEQ ID NO:2 itself, the claim encompasses a large number of inoperative nucleic acids which the artisan would not know how to use. It is suggested that a specific functional limitation, such as "which is useful for the production of an antibody that binds to a polypeptide of SEQ ID NO:2" be added to limit the scope of the invention. Claims 6, 7, and 9 depend from claim 3.

Applicants Response

Claim 3 has been so amended.

- (2) Claim 11(b) recites a polynucleotide comprising a naturally occurring polynucleotide

sequence at least 90% identical to SEQ ID NO:2. Since the claims does not require a functional limitation, such as encoding a protein having thioredoxin activity, and the specification fails to provide sufficient directions to guide an artisan to use those variants that do not have the same functions as SEQ ID NO:4.

Applicants Response

Claim 11 has been amended to recite the additional limitation that a variant of the polynucleotide sequence of SEQ ID NO:4 having at least 90% identity to SEQ ID NO:4 further encode a protein having thioredoxin activity.

(3) Claim 12 recites an isolated polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO:4 or its natural variants. However, other than the polynucleotide sequence of SEQ ID NO:4 encoding the polypeptide of SEQ ID NO:2, the specification fails to provide sufficient guidance, information or working examples regarding structural and functional requirements commensurate in scope with what is encompassed by the claims. If Applicants intend to claim the use of such nucleic acids as probes or primers, they should clearly indicate so and the binding target of the probes or primers. If Applicants intend to claim such nucleic acids as protein encoding sequence, they should limit the nucleic acid by indicating the biological function of the protein/fragments encoded by the claimed nucleic acids.

Applicants Response

Claim 12 has been amended to recite a “polynucleotide probe” and to further identify the target polynucleotide of said probe as the “complete complement” of a polynucleotide of claim 11.

With these amendments and remarks, Applicants submit that the claims are fully enabled by the specification, and withdrawal of the rejection of claims 3, 4, 6, 7, 9, 11 and 12 under 35 U.S.C. § 112, first paragraph for lack of enablement is requested.

35 U.S.C. § 112, First Paragraph, Rejection of Claims 3, 6, 7, 9 and 11 (Written Description)

The Examiner has maintained the rejection of claims 3, 6, 7, 9, 11 and 12 under 35 U.S.C. § 112, first paragraph (Written Description) for the reasons of record of the previous Office Action.

The Examiner stated that Applicants arguments presented in the previous response filed December 22, 2003 have been considered, but are not deemed to be persuasive for the following reasons. First while claim 3 (b) and 3(c) has been amended to recite a functional limitation, claim 11(b) has not been so amended. Secondly, the specification fails to disclose functional natural variants at least 90% identical to SEQ ID NO:4 and furthermore fails to teach how to distinguish a naturally occurring amino acid sequence from a non-naturally occurring one. It is suggested, therefore, that “a naturally occurring amino acid sequence” be replaced by “an amino acid sequence” to overcome the rejection of claim 3(b) and 11(b).

It is further noted, the Examiner stated, that the rejection of claim 3(d) and 12 under 35 U.S.C. § 112, first paragraph (Written Description) also remains. Applicants have not specifically addressed these issues. It is suggested that a specific functional limitation be added to these claims to overcome the rejection.

Applicants Response

The amendment to claim 11 adding a functional limitation to the claimed variants has been previously discussed. Regarding the issue of how one skilled in the art would distinguish a “naturally occurring” amino acid sequence from a non-naturally occurring one, Applicants submit that this would be merely a matter of determining whether or not a given sequence was isolated from a biological source or detected in a biological sample, and which would not require a specific teaching in the specification. However, to overcome this part of the rejection, claims 3(b) and 11(b) have been amended to delete the phrase “naturally occurring”. With respect to the rejection of claims 3(d) and 12 under this section, Applicants have addressed this issue as indicated in the response to rejection of these claims under 35 U.S.C. § 112, first paragraph regarding enablement, above.

With these amendments and remarks, Applicants submit that the claims are adequately described in accordance with 35 U.S.C. § 112, first paragraph and request withdrawal of the rejection of claims 3, 6, 7, 9, 11 and 12 under 35 U.S.C. § 112, first paragraph.

VI Claim Objections

(1) The objection of claim 9 for being dependent on unelected claim 1 is maintained. Applicants have not fully amended the claim yet.

Claim 9 has been amended to depend from only elected claim 3.

(2) The amended claim 9 is also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only.

Claim 3 has been amended as previously discussed to depend from only claim 3.

(3) The objection of claim 46 as being a substantial duplicate to claim 5 remains. Applicants have not amended the claims. It is also suggested that "A polynucleotide" be replaced by "An isolated polynucleotides" in claim 46.

Claim 46 has been so amended.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding objections/rejections. Early notice to that effect is earnestly solicited. Applicants further request that upon allowance of product claims 5 and 11, claims 13-15 and 27-28 be rejoined and examined as process claims that depend from and are of the same scope as the allowed product claims in accordance with *In re Ochiai* and the MPEP § 821.04.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108**.

Respectfully submitted,

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